VOID SHEET

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WICLEAR REGULA,

UNITED STATES NUCLEAR REGULATORY COMMISSION

REGION IV

611 RYAN PLAZA DRIVE, SUITE 400 ARLINGTON, TEXAS 76011-8064

REGIONAL TECHNICAL ASSISTANCE REQUEST FORM

(CONTINUATION)

Date: July 27, 1994

Mail or E-Mail to: Carl J. Paperiello (CJP1), Mail Stop: 8F5-TWFN

Division of Industrial and Medical Nuclear Safety, NMSS

From: Samuel J. Collins, Director Region IV

Division of Radiation Safety and Safeguards

Licensee: Department of Veterans Affairs

License No.: 03-01082-01

Little Rock, Arkansas

Department of Veterans Affairs License No.: 26-00138-10

Omaha, Nebraska

X Control Nos. 465296 465241

X Letters dated: June 23, 1994 and May 16, 1994

Problem/Issue:

In a Technical Assistance Request (TAR) dated September 30, 1993, Region IV submitted the original requests for Department of Veterans Affairs (VA) - Denver. Colorado, Department of VA - Salt Lake City, Utah. Department of VA - Omaha. Nebraska, and Department of VA - Little Rock, Arkansas to downgrade VA broad scope licenses to a "hybrid broad scope license" category. Department of VA - Little Rock, Arkansas and Department of VA - Omana, Nebraska have submitted detailed additional information regarding the proposed changes in license status from broad scope to limited scope.

□ Action Required:

Review the submitted information and provide guidance for response to Department of VA - Little Rock, Arkansas, Department of VA - Denver, Colorado, Department of VA - Omaha, Nebraska, and Department of VA - Salt Lake City, Utah.

Headquarter Reviewer: Dr. Donna-Beth Howe

Regional Reviewer:

Jack E. Whitten/Jacqueline D. Burks

Senior Health Physicist/Health Physicist

Reviewer Code:

T1/T9

Reviewer Phone No.:

817-860-8197/817-860-8132

FAX No.: 817-860-8188

Request Needed by:

08/17/94

Form TAR-10

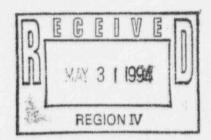
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DEPARTMENT OF VETERANS AFFAIRS Medical Center St Louis MO 63125

May 20, 1994

U.S. Nuclear Regulatory Commission Region IV 611 Ryan Plaza Drive Arlington, TX 76011 In Reply Refer To:



The enclosed correspondence from the Omaha, Nebraska VA Medical Center has been received and is forwarded to your office for processing. If there are questions, please contact the facility.

Please provide a copy of any correspondence relative to licensing actions for this Medical Center to:

Department of Veterans Affairs Health Physics Programs (115HP) 915 North Grand Blvd. St. Louis, MO 63106

Sincerely,

Francis K. Herbig

Health Physics Programs

_ = = = 41



May 16, 1994

In Reply Refer To:

636/151C

U.S. Nuclear Regulatory Commission Region IV 611 Ryan Plaza Drive, Suite 400 Arlington, TX 76011-8064

Reference: License No. 26-00138-10

Subject: Broad scope to limited scope license amendment

On September 23, 1994, the Omaha Department of Veterans Affairs Medical Center filed a request to change our Broad scope byproduct materials license to a medical and research/development limited scope license. The request was faxed to your office on Sept. 23, 1993 and the original mailed on the same date (see attached documentation). The attached amendment request is a continuation of this process.

Sincerely,

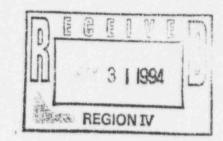
JOHN J. PHILLIPS

Director

Enclosures:

Fax documentation

Express Mail receipt



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J.V. Scalear Regulatory Commission Pagina 19 vil Syon Plaza Ar., Scite 100 -1119gton, F. 70011-5061



May 16, 1994

In Reply Refer To:

636/151C

U.S. Nuclear Regulatory Commission Region IV 611 Ryan Plaza Drive, Suite 400 Arlington, TX 76011-806

Reference: Material License No. 26-00138-10

Subject: Broad scope to limited scope license amendment

1. Amendment request:

The Omaha VA Medical Center desires to change through amendment from the current Broad Scope license to a <u>medical and research/development limited scope</u> license while retaining flexibility to manage the program locally through the Radiation Safety Committee (RSC) and thus avoid the frequent need for processing amendment requests through the NRC. Specifically, we request that the license amendment specify by line items that the RSC will have authority to:

- a. Approve medical authorized users according to the strict criteria set forth in 10 CFR Part 35. Subpart J. For applicants who do not meet the Subpart J criteria for clinical uses of regulated materials an amendment request will be sent to the Commission for action.
- b. Approve <u>medical uses</u> of regulated materials only as authorized by 10 CFR Part 35.
- c. Approve non-human research development users and uses of regulated materials. The standards for approving local authorized users will include possession of a bachelor level college degree in physical or biologic science or in engineering and at least forty hours of training and experience in the safe handling of radioactive materials, radiation characteristics. units of radiation dose and quantity, detection instrumentation, and health hazards associated with radiation exposure (10 CFR Part 33.15 (b), (1 and 2). If 40 hours can not be documented the procedure outlined in par. 1.5b3 of our letter of Feb. 11,1993, Docket No. 030-02409 will be followed. Additionally RSC approval of the applicant will require demonstrable training, experience and knowledge related to surveying areas and/or measurement of contamination by radionuclides of the kinds requested or with similar types of nuclear radiation emitters.

d. Approve the use of facilities and equipment for research and medical uses and approve locations and relocations of approved activities on the licensed premises. Approval of facilities will require evaluation of ventilation, shielding, contamination confinement, instrumentation and such other items as is needed to assure the RSC that requested uses can be conducted safely. Authorization of users is inseparately linked to approval of user facilities.

Designation of previous use areas in the facility as unrestricted areas will require that the NRC guidelines for ambient radiation levels and residual contamination are not exceeded. Records will be maintained which demonstrate

compliance with unrestricted area requirements.

e. Approve, with the concurrence of the Radiation Safety Officer and Medical Center management, changes to the facility radiation safety program which are administrative in nature or changes which do not adversely effect or reduce requirements for safe procedures and a safe work environment. Program changes must be specifically evaluated prospectively and reviewed by the RSC at least once to assure that the goals of change are met and that safety is not compromised. The RSC may not approve exceptions to the NRC regulations.

2. Commitments. Limitations and Understandings:

- a. The RSC will remain broadly constituted as is expected for Broad Scope programs, represent clinical and research and development uses and users, include experts in radiation safety and program management and fully meet the regulatory requirements for composition described in Part 35.
- b. The RSC will not authorize uses of regulated materials in humans for clinical or research purposes which are not authorized by 10 CFR Part 35. Research involving human subjects will require prior license amendment by the NRC.
- c. Possession limits of regulated materials will be specified in the VA license application/amendment request and must be approved by the NRC. The broad authority for possession of approved Part 35 medical byproduct materials in quantities as needed will be retained in the authority granted by the license. (see Attachment A)
- d. The RSC and Medical Center management recognize the Committee's responsibility to meet the requirements of 10 CFR Part 35.22, 23. Beyond these specified responsibilities and those described in the five points (l.a.-e.) above, the NRC has sole authority to approve and regulate the elements of our program.
- e. Facilities approved for licensed activities are as described in Item 9 of our application for a broad license dated Jan. 14, 1993 and letter dated Feb. 11, 1993. The RSC

will evaluate new facilities on the licensed premises using criteria appropriate to the intended uses. (see 1.d. above)

- f. All other statements in our Application of Jan. 14, 1993 and our letter dated Feb. 11, 1993 apply.
- 3. An application for amendment requesting conversion of our license to a "hybrid" type was filed with your office on September 23, 1993. This information is intended to supplement that request and specifies the correct license category, "limited scope". The changes in program codes as a result of this licensing action are expected to significantly reduce the annual fee charged to this facility in FY-94 and, therefore, your prompt consideration of this request will be appreciated.
- 4. You may contact our Radiation Safety Officer, Alan J. Blotcky at (402) 346-8800, Ext. 3002 with any questions or needed clarifications concerning this amendment request.

Sincerely,

JOHN J. PHILLIPS Director

Attachments A

Omaha VA Medical Center

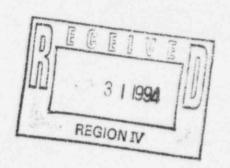
Request for Licensed Materials

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	Zn-71	any	50 millicuries		

Calibration Sources

I-125	Sealed sources	2 millicuries
Cs-137	Sealed source (J. L Shepherd Model No. 6810)	1500 curies
Cs-137	Sealed source (J.L. Shepherd Model 28-6A Calibrator)	1.2 curies
Cs-137	Sealed sources	500 millicuries
Am-241	Sealed sources	Not to exceed 15 millicuries per source ¹
Ba-133	Sealed sources	2 millicuries
Co-60	Sealed sources	10 millicuries
Eu-152	Sealed sources	10 microcuries
I-129	Sealed sources	5 microcuries



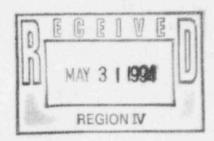
1. For use in anatomical markers and dual isotope motion correction devices.



DEPARTMENT OF VETERANS AFFAIRS Medical Center St Louis MO 63125

May 20, 1994

U.S. Nuclear Regulatory Commission Region IV 611 Ryan Plaza Drive Arlington, TX 76011 In Reply Refer To:



The enclosed correspondence from the Omaha, Nebraska VA Medical Center has been received and is forwarded to your office for processing. If there are questions, please contact the facility.

Please provide a copy of any correspondence relative to licensing actions for this Medical Center to:

Department of Veterans Affairs Health Physics Programs (115HP) 915 North Grand Blvd. St. Louis, MO 63106

Sincerely,

Francis K. Herbig

Health Physics Programs



May 16, 1994

In Reply Refer To:

636/151C

Department of Veterans Affairs National Health Physics Program (115HP) 915 North Grand Boulevard St. Louis, MO 63106

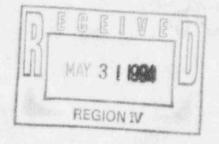
Subject: Broad Scope to Limited Scope License Amendment

Attached is the Broad scope to limited scope license amendment as suggested by your letter of April 20, 1994. The amendment request has been approved by the Radiation Safety Committee and the Radiation Safety Officer. Please forward the document to the NRC as you requested.

Sincerely,

JOHN J. PHILLIPS

Director





May 16, 1994

In Reply Refer To:

636/151C

U.S. Nuclear Regulatory Commission Region IV 611 Ryan Plaza Drive, Suite 400 Arlington, TX 76011-8064

Reference: License No. 26-00138-10

Subject: Broad scope to limited scope license amendment

On September 23, 1994, the Omaha Department of Veterans Affairs Medical Center filed a request to change our Broad scope byproduct materials license to a medical and research/development limited scope license. The request was faxed to your office on Sept. 23, 1993 and the original mailed on the same date (see attached documentation). The attached amendment request is a continuation of this process.

Sincerely,

JOHN J. PHILLIPS

Director

Enclosures: Fax documentation

Express Mail receipt

DEPARTMENT OF VETERANS AFFAIRS MEDICAL CENTER

OMAHA, NEBRASKA

ssion

PLEASE DELI	VER TO			
NAME		U.S. A	luclean	Regulatory Commi
LOCATI	ON:	Region 1	V. Ar	lington, TX
MAIL C	ODE			
FAX #	:	817-	860 -	8210
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		ALL THE PAGES,		BACK AS SOON AS POSSIBLE.
PTS: COMMERCIAL:	(700) (402)	860-3755 449-0684		860-3100 449-0600
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May 16, 1994

In Reply Refer To:

636/151C

U.S. Nuclear Regulatory Commission Region IV 611 Ryan Plaza Drive, Suite 400 Arlington, TX 75011-806

Reference: Material License No. 26-00138-10

Subject: Broad scope to limited scope license amendment

1. Amendment request:

The Omaha VA Medical Center desires to change through amendment from the current Broad Scope license to a <u>medical and research/development limited scope</u> license while retaining flexibility to manage the program locally through the Radiation Safety Committee (RSC) and thus avoid the frequent need for processing amendment requests through the NRC. Specifically, we request that the license amendment specify by line items that the RSC will have authority to:

- a. Approve <u>medical authorized users</u> according to the strict criteria set forth in 10 CFR Part 35. Subpart J. For applicants who do not meet the Subpart J criteria for clinical uses of regulated materials an amendment request will be sent to the Commission for action.
- b. Approve <u>medical uses</u> of regulated materials only as authorized by 10 CFR Part 35.
- c. Approve non-human research development users and uses of regulated materials. The standards for approving local authorized users will include possession of a bachelor level college degree in physical or biologic science or in engineering and at least forty hours of training and experience in the safe handling of radioactive materials, radiation characteristics. units of radiation dose and quantity, detection instrumentation, and health hazards associated with radiation exposure (10 CFR Part 33.15 (b), (1 and 2). If 40 hours can not be documented the procedure outlined in par. 1.5b3 of our letter of Feb. 11,1993, Docket No. 030-02409 will be followed. Additionally RSC approval of the applicant will require demonstrable training, experience and knowledge related to surveying areas and/or measurement of contamination by radiomyclides of the kinds requested or with similar types of nuclear radiation emitters.

d. Approve the use of facilities and equipment for research and medical uses and approve locations and relocations of approved activities on the licensed premises. Approval of facilities will require evaluation of ventilation, shielding, contamination confinement, instrumentation and such other items as is needed to assure the RSC that requested uses can be conducted safely. Authorization of users is inseparately linked to approval of user facilities.

Designation of previous use areas in the facility as unrestricted areas will require that the NRC guidelines for ambient radiation levels and residual contamination are not exceeded. Records will be maintained which demonstrate

compliance with unrestricted area requirements.

e. Approve, with the concurrence of the Radiation Safety Officer and Medical Center management, changes to the facility radiation safety program which are administrative in nature or changes which do not adversely effect or reduce requirements for safe procedures and a safe work environment. Program changes must be specifically evaluated prospectively and reviewed by the RSC at least once to assure that the goals of change are met and that safety is not compromised. The RSC may not approve exceptions to the NRC regulations.

2. Commitments. Limitations and Understandings:

- a. The RSC will remain broadly constituted as is expected for Broad Scope programs, represent clinical and research and development uses and users, include experts in radiation safety and program management and fully meet the regulatory requirements for composition described in Part 35.
- b. The RSC will not authorize uses of regulated materials in humans for clinical or research purposes which are not authorized by 10 CFR Part 35. Research involving human subjects will require prior license amendment by the NRC.
- c. Possession limits of regulated materials will be specified in the VA license application/amendment request and must be approved by the NRC. The broad authority for possession of approved Part 35 medical byproduct materials in quantities as needed will be retained in the authority granted by the license. (see Attachment A)
- d. The RSC and Medical Center management recognize the Committee's responsibility to meet the requirements of 10 CFR Part 35.22, 23. Beyond these specified responsibilities and those described in the five points (l.a.-e.) above, the NRC has sole authority to approve and regulate the elements of our program.
- e. Facilities approved for licensed activities are as described in Item 9 of our application for a broad license dated Jan. 14, 1993 and letter dated Feb. 11, 1993. The RSC

will evaluate new facilities on the licensed premises using criteria appropriate to the intended uses. (see 1.d. above)

- f. All other statements in our Application of Jan. 14, 1993 and our letter dated Feb. 11, 1993 apply.
- 3. An application for amendment requesting conversion of our license to a "hybrid" type was filed with your office on September 23, 1993. This information is intended to supplement that request and specifies the correct license category, "limited scope". The changes in program codes as a result of this licensing action are expected to significantly reduce the annual fee charged to this facility in FY-94 and, therefore, your prompt consideration of this request will be appreciated.
- 4. You may contact our Radiation Safety Officer, Alan J. Blotcky at (402) 346-8800, Ext. 3002 with any questions or needed clarifications concerning this amendment request.

Sincerely,

JOHN J. PHILLIPS

Director

Attachments A

Omaha VA Medical Center

Request for Licensed Material

Radionuclide	Form	Possession Limit
Human Use Materials		
As specified in Part 35.100	Any identified in Part 35.100	as needed
As specified in Part 35.200	Any identified in Part 35.200	as needed
As specified in Part 35.300	Any identified in Part 35.300	as needed
As specified in Part 35.400	Any identified in Part 35.400	as needed
non-Human Research Ma	terials	
H-3 C-14 P-32 Cr-51 TC-99m I-125 Au-198 Ag-108 Ag-10m Al-28 As-76 Ba-138 Br-80 Br-80m Br-82 Br-82m Ca-45 Ca-47	any	500 millicuries 500 millicuries 500 millicuries 200 millicuries 1 curie 500 millicuries 300 millicuries 50 millicuries
Ca-49 Cd-107 Cd-111m Cd-115 C1-36 C1-38	any any any any any	50 millicuries 50 millicuries 50 millicuries 50 millicuries 50 millicuries 50 millicuries

Radionuclide	Form	Possession Limit
non-Human Research M	aterials	
Ce-139 Co-60 Co-60m Cr-51	any any any	2 microcuries 50 millicuries 50 millicuries 50 millicuries
Cr-55 Cu-64 Cu-66 Fe-59	any any any any any	50 millicuries 50 millicuries 50 millicuries 50 millicuries 50 millicuries
Gd-159 Gd-161 Hg-197 Hg-197m	any any any	50 millicuries 50 millicuries 50 millicuries 50 millicuries 50 millicuries
Hg-199m Hg-203 Hg-205 I-128 I-131	any any any any any	50 millicuries 50 millicuries 50 millicuries 50 millicuries
In-111 K-42 Mg-27 Mn-54 Mn-56	any any any any any	50 millicuries 50 millicuries 50 millicuries 50 millicuries 50 millicuries
Na-24 Ni-65 Pt-197 Pt-197m	any any any any	50 millicuries 50 millicuries 50 millicuries 50 millicuries
Pt-199 S-35 S-37 Se-75 Se-81	any any any any any	50 millicuries 50 millicuries 50 millicuries 50 millicuries 50 millicuries
Si-31 Sm-153 Sm-155 Sn-113 Sn-123	any any any any any	50 millicuries 50 millicuries 50 millicuries 50 millicuries 50 millicuries
Sn-125 Sr-85 Sr-87 Sr-89 V-52	any any any any any	50 millicuries 50 millicuries 50 millicuries 50 millicuries 50 millicuries
Y-88 Y-90 Zn-65 Zn-69 Zn-69m	any any any any	50 millicuries 50 millicuries 50 millicuries 50 millicuries 50 millicuries
Zn-71	any	50 millicuries

Calibration Sources

I-125	Sealed sources	2 millicuries
Cs-137	Sealed source (J. L Shepherd Model No. 6810)	1500 curies
Cs-137	Sealed source (J.L. Shepherd Model 28-6A Calibrator)	1.2 curies
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Ba-133	Sealed sources	2 millicuries
Co-60	Sealed sources	10 millicuries
Eu-152	Sealed sources	10 microcuries
I-129	Sealed sources	5 microcuries



 For use in anatomical markers and dual isotope motion correction devices.